UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF OHIO
EASTERN DIVISION

IN RE: DAVOL, INC./C.R. BARD, INC., POLYPROPYLENE HERNIA MESH PRODUCTS LIABILITY LITIGATION

Case No. 2:18-md-2846

JUDGE EDMUND A. SARGUS, JR.
Magistrate Judge Kimberly A. Jolson

This document relates to:
***Milanesi v. C.R. Bard*,**
Case No. 2:18-cv-01320

MOTIONS IN LIMINE OPINION AND ORDER NO. 35

Defendants' Motion *in Limine* ("MIL") No. 8

Defendants C.R. Bard, Inc. and Davol, Inc. filed a Motion *in Limine* to Exclude Evidence and Argument Concerning Alleged Fraud on the FDA, Misbranding, or Violation of FDA Regulations (Defendants' MIL No. 8, ECF No. 173), which is opposed by Plaintiffs Antonio Milanesi and Alicia Morz de Milanesi (ECF No. 227). For the reasons that follow, the Court **DENIES** Defendants' MIL No. 8.

I. Background[1]

The Milanesis' case will be tried as the second bellwether selected from thousands of cases in this multidistrict litigation ("MDL") titled *In Re: Davol, Inc./C.R. Bard, Inc., Polypropylene Hernia Mesh Products Liability Litigation*, 2:18-md-2846. The Judicial Panel on Multidistrict Litigation described the cases in this MDL as "shar[ing] common factual questions arising out of

[1] For a more complete factual background, the reader is directed to the Court's summary judgment opinion and order in this case *Milanesi v. C.R. Bard*, Case No. 2:18-cv-01320. (ECF No. 167.) All docket citations are to the *Milanesi* case, 2:18-cv-1320, unless otherwise noted.

allegations that defects in defendants' polypropylene hernia mesh products can lead to complications when implanted in patients, including adhesions, damage to organs, inflammatory and allergic responses, foreign body rejection, migration of the mesh, and infections." (Case No. 2:18-md-02846, ECF No. 1 at PageID #1–2.)

Plaintiffs bring this action to recover for injuries sustained as a result of the implantation of the Ventralex Large Hernia Patch, alleging that Defendants knew of the risks presented by the device but marketed and sold it despite these risks and without appropriate warnings. After summary judgment, the following claims remain for trial: defective design (strict liability), failure to warn (strict liability), negligence, gross negligence, negligent misrepresentation, fraud and fraudulent misrepresentation, fraudulent concealment, loss of consortium, and punitive damages.

The relevant facts here are that Mr. Milanesi underwent surgery to repair what appeared to be a recurrent hernia but was revealed to be a bowel erosion with a fistula and adhesions, which required a bowel resection. Shortly thereafter, Mr. Milanesi suffered a high-grade post-operative small bowel obstruction that required emergency surgery. Mr. Milanesi had the Ventralex Large Hernia Patch implanted ten years earlier to repair a hernia.

In Defendants' MIL No. 8, they move to exclude under Federal Rules of Evidence 401, 402, 403, and 404(b) evidence or argument concerning alleged fraud on the FDA, misbranding, or violation of FDA regulations. (Defs' MIL No. 8, ECF No. 173.)

II. Standards

"Neither the Federal Rules of Evidence nor the Federal Rules of Civil Procedure explicitly authorize a court to rule on an evidentiary motion *in limine*." *In re E.I. du Pont de Nemours & Co. C-8 Pers. Injury Litig.*, 348 F. Supp. 3d 698, 721 (S.D. Ohio 2016). The practice of ruling on such motions "has developed pursuant to the district court's inherent authority to manage the course of

trials." *Luce v. United States*, 469 U.S. 38, 41 n.4 (1984). "The purpose of a motion *in limine* is to allow a court to rule on issues pertaining to evidence prior to trial to avoid delay and ensure an evenhanded and expedient trial." *In re E.I. du Pont*, 348 F. Supp. 3d at 721 (citing *Ind. Ins. Co. v. Gen. Elec. Co.*, 326 F. Supp. 2d 844, 846 (N.D. Ohio 2004)). However, courts are generally reluctant to grant broad exclusions of evidence before trial because "a court is almost always better situated during the actual trial to assess the value and utility of evidence." *Koch v. Koch Indus., Inc.*, 2 F. Supp. 2d 1385, 1388 (D. Kan. 1998); *accord Sperberg v. Goodyear Tire & Rubber Co.*, 519 F.2d 708, 712 (6th Cir. 1975). Unless a party proves that the evidence is clearly inadmissible on all potential grounds—a demanding requirement—"evidentiary rulings should be deferred until trial so that questions of foundation, relevancy and potential prejudice may be resolved in proper context." *Ind. Ins. Co.*, 326 F. Supp. 2d at 846; *see also Koch*, 2 F. Supp. 2d at 1388 ("[A] court is almost always better situated during the actual trial to assess the value and utility of evidence."). The denial, in whole or in part, of a motion *in limine* does not give a party license to admit all evidence contemplated by the motion; it simply means that the Court cannot adjudicate the motion outside of the trial context. *Ind. Ins Co.*, 326 F. Supp. 2d at 846.

Relevant evidence is "evidence having any tendency to make the existence of any fact that is of consequence to the determination of the action more probable or less probable than it would be without the evidence." Fed. R. Evid. 401. "Irrelevant evidence is" inadmissible. Fed. R. Evid. 402. A court may exclude relevant evidence under Federal Rule of Evidence 403 "if its probative value is substantially outweighed by a danger of . . . unfair prejudice, confusing the issues, misleading the jury, undue delay, wasting time, or needlessly presenting cumulative evidence." Fed. R. Evid. 403. Evidentiary rulings are made subject to the district court's sound discretion. *Frye v. CSX Trans., Inc.*, 933 F.3d 591, 598 (6th Cir. 2019); *see also Paschal v. Flagstar Bank*,

295 F.3d 565, 576 (6th Cir. 2002) ("In reviewing the trial court's decision for an abuse of discretion, the appellate court must view the evidence in the light most favorable to its proponent, giving the evidence its maximum reasonable probative force and its minimum reasonable prejudicial value."). Rule 404(b) prohibits "[e]vidence of a crime, wrong, or other act" to "prove a person's character in order to show that on a particular occasion that person acted in accordance with the character." Fed. R. Evid. 404(b).

III. Analysis

Both parties agree that a similar issue was before this Court in the first bellwether case, *Johns v. C. R. Bard, Inc., et al.*, Case No. 2:18-cv-01509. The Court denied Defendants' motion to exclude evidence or argument of alleged fraud on the FDA, misbranding, or violation of FDA regulations. (Case No. 2:18-cv-01509, MIL Order No. 2, ECF No. 331 at PageID #17886; Case No. 2:18-cv-01509, MIL Order No. 4, ECF No. 355 at PageID #18769–72.) In denying Defendants' motion in part, the Court stated that "[t]he parties may present certain evidence related to information submitted or omitted in the course of the 510(k) clearance of [Defendants'] Ventralight ST, but the Court will provide an instruction to the jury regarding the statutory and regulatory requirements for the 510(k) process[.]" (Case No. 2:18-cv-01509, MIL Order No. 2, ECF No. 331 at PageID #17886.) The Court issued a more detailed ruling on Defendants' motion in its MIL Order No. 8, in which the Court reasoned:

> In their Motion in Limine No. 8, Defendants argue that evidence and argument related to alleged fraud on the FDA, misbranding, and violations of FDA regulations should be excluded. (ECF No. 209). . . . Defendants argue that this evidence is preempted by *Buckman v. Plaintiffs' Legal Committee*, 531 U.S. 341 (2001), whether cast as a fraud-on-the-FDA claim or a claim under state tort law, and is unfairly prejudicial. (*Id.* at 782.) The Court denied this motion in part. (ECF No. 331 at PageID #17886.)
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> In *Buckman*, the Supreme Court held that claims based on fraud against the FDA brought under state law were impliedly preempted by the FDCA as amended by the Medical Device Amendments of 1976. 531 U.S. at 344. But the Court was

careful to exclude state-tort-law claims from the scope of preemption stemming from the 1976 Amendments to the FDCA. First, the Court distinguished a previous case where the claims were based "on traditional state tort law principles." *Id.* at 351–52 (discussing *Silkwood v. Kerr-McGee Corp.*, 464 U.S. 238 (1984)). The Court then "reject[ed] respondent's attempts to characterize both the claims at issue in *Medtronic* (common-law negligence against the manufacturer of an allegedly defective pacemaker lead) and fraud claims here 'as claims arising from violations of [§ 510(k) process application requirements set forth by statute].'" *Id.* at 352. The Court so because those "claims arose from the manufacturer's alleged failure to use reasonable care in the production of the product, *not solely from the violation of FDCA requirements*." *Id.* (alterations in original) (emphasis added). Because the claims in *Buckman* "exist[ed] solely by virtue of the FCDA disclosure requirements," the claims were preempted. *Id.* at 353; *see also id.* ("[T]he existence of these federal enactments is a critical element of their case.").

The Sixth Circuit has not interpreted *Buckman* more broadly and has consistently found that only claims premised upon violations of the FDCA or FDA regulations are preempted.[2] In *Fulgenzi v. PLIVA, Inc.*, the court explained that *Buckman* applies only to claims that depend "on a federal-law violation" as "a link in the causal chain or element of the claim." 711 F.3d 578, 588 (6th Cir. 2013). The Sixth Circuit counseled caution "in extending the reasoning of *Buckman* to claims in which the presumption [against preemption] applies, such as the traditional state-tort-law claims" because such claims do not bear greatly on "'federalism concerns,'" which is the basis of the doctrine of preemption, and instead implicate "'the historic primacy of state regulation of matters of health and safety.'" *Id.* at 586 n.3 (quoting *Buckman*, 531 U.S. at 348). Circuit precedent interpreting *Buckman* has been consistent, explaining that the claims preempted are those that "'require[ ] proof of fraud committed against the FDA' to succeed." *Marsh v. Genentech, Inc.*, 693 F.3d 546, 551 (6th Cir. 2012) (quoting *Garcia v. Wyeth-Ayerst Labs.*, 385 F.3d 961, 965–66 (6th Cir. 2004)).

Undoubtedly, a fraud-on-the-FDA claim could be presented as a state-law-tort claim, and so federal courts must consider the substance of a claim. *Loreto v. Procter & Gamble Co.*, 515 F. App'x 576, 579 (6th Cir. 2013). But the guiding inquiry is simple—could the claim "exist in the absence of the FDCA?" *Id.* For example, preemption was warranted when a Michigan statute provided tort immunity to drug manufacturers unless they failed to comply with FDA requirements. *Garcia*, 385 F.3d at 966. Such a defense required and was dependent on the defendant's noncompliance with FDA requirements. *Id.* Similarly, when a

[2] When interpreting federal law, such as the preemptive force of *Buckman*, a transferee federal court applies the circuit precedent of the circuit in which it sits. *See In re U.S. Dep't of Defense and U.S. EPA Final Rule*, 817 F.3d 261, 272 (6th Cir. 2016) (citing *Murphy v. FDIC*, 2038 F.3d 959, 964–65 (11th Cir. 2000)), *rev'd and remanded on other grounds*, *Nat'l Ass'n of Mfrs. v. Dep't of Defense*, 138 S. Ct. 617 (2018); *In re Cardizem CD Antitrust Litig.*, 332 F.3d 896, 911 n.17 (6th Cir. 2003) (noting "that in federal multidistrict litigation there is a preference for applying the law of the transferee district"); *see also In re Porsche Cars N. Am.*, 880 F. Supp. 2d 801, 815 (S.D. Ohio 2012); *In re Nat'l Century Fin. Enterprises, Inc., Inv. Litig.*, 323 F. Supp. 2d 861, 876–77 (S.D. Ohio 2004).

> plaintiff had expressly disclaimed any reliance on state-law failure-to-warn claims and relied exclusively on noncompliance with FDA regulations, the claim was preempted. *McDaniel v. Upsher-Smith Labs., Inc.*, 893 F.3d 941, 944–46 (6th Cir. 2018).
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> Plaintiff's claims here are state-law-tort claims that do not solely depend on violations of the FDCA or FDA regulations. The crux of Plaintiff's case is that Defendants failed to exercise reasonable care in designing and marketing the Ventralight ST. If the FDCA and all the accompanying FDA regulations were repealed tomorrow, Plaintiff could still rely on state-law negligence and strict-liability principles to bring these claims. And under Utah state law, federal statutes and regulations help define the duty of care, but federal law alone does not set the duty of care. *See Downing*, 194 P.3d at 948. Thus, Plaintiff's claims are not preempted by *Buckman*.
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> Defendants attempt to stretch *Buckman* further than precedent permits. They argue that claims may not be premised upon violations of federal law and then assert that evidence referring to noncompliance with federal requirements is tantamount to such a claim. (ECF No. 209 at PageID #11788–89.) There is no support for this assertion. *Buckman* holds that the FDCA preempts claims, not evidence. *Fulgenzi* is clear about this distinction, explaining that even if "the logic of *Buckman* would encourage exclusion of evidence of federal-law violations where possible," evidence of federal-law violations is admissible when "federal law bears on the state duty of care." 711 F.3d at 588. Or, put even more succinctly: "[i]f such evidence is relevant, *Buckman* is no bar to its admission." *Id.* Even negligence per se claims may incorporate violations of the FDCA requirements. *Id.* (collecting cases). Defendants' gloss on what constitutes a *Buckman* claim is exceptionally hard to square with *Fulgenzi* and other Sixth Circuit precedent that emphasizes that *claims* which turn on only federal-law violations are preempted.
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> Finally, Defendants also encourage exclusion of any evidence that they failed to comply with FDCA or FDA regulatory requirements because that evidence will confuse or mislead a jury, encouraging the jury to conclude that Defendants' purported failure to comply with the federal requirements means Defendants necessarily failed to satisfy their state-law duty of care. (ECF No. 209 at PageID #11789.) Any possibility of juror confusion on this matter is rectified with an instruction. Much like the ISO standards, evidence of federal requirements and whether Defendants complied with them is admissible. An instruction shall be given to the jury, explaining that the federal requirements are evidence of the duty of care and of whether Defendants' actions were reasonable, but not conclusive evidence that Defendants failed to satisfy the duty of reasonable care.

(Case No. 2:18-cv-01509, MIL Order No. 4, ECF No. 355 at PageID #18769–72.) The Court adopts its prior ruling in *Johns*.

Defendants' argument in their Motion largely relies on the Court's summary judgment

ruling on the Plaintiffs' negligence *per se* claim. However, as Plaintiffs point out in their response, evidence of violation of a statute or regulation can be evidence of negligence. (Pls' Mem. in Opp., ECF No. 227 at PageID #15258; *see also* Dispositive Motions Order No. 3, ECF No. 167 at PageID #13635 ("[V]iolation of a statute or regulation is simply evidence of negligence.").) Therefore, the fact that the Court granted summary judgment to the Defendants on Plaintiffs' negligence *per se* claim does not mean that any evidence of statutes or regulations is inadmissible.

IV. Conclusion

For the reasons set forth above, the Court **DENIES** Defendants' MIL No. 8 (ECF No. 173).

As with all *in limine* decisions, this ruling is subject to modification should the facts or circumstances at trial differ from that which has been presented in the pre-trial motion and memoranda.

IT IS SO ORDERED.

12/13/2021
DATE

s/Edmund A. Sargus, Jr.
EDMUND A. SARGUS, JR.
UNITED STATES DISTRICT JUDGE